

17th October 2022

URGENT: FIELD SAFETY NOTICE

Urgent Information regarding the Omnipod DASH® Insulin Management System

FSCA REF: 9056196-10/11/2022-001-C

Affected Product:

Device Description	Part Number	Serial Number
Omnipod DASH® Personal Diabetes Manager (PDM)	PT-000011 PT-000019-GBR-ENG	All serial numbers

Please read this notice in its entirety and acknowledge receipt and understanding of this notice.

Dear Valued Customer,

You are receiving this communication as our records indicate you are a new user of the Omnipod DASH® Insulin Management System. This notice is being communicated as a voluntary Field Safety Notification to provide information about the Omnipod DASH Personal Diabetes Manager (PDM) battery and instructions to reduce the risk of Omnipod DASH PDM battery issues. It is important to note that no injuries have been reported to Insulet as a result of these Omnipod DASH PDM battery issues.

This does NOT affect the Omnipod DASH Pods or the Omnipod® Insulin Management System.

Issue Description: We have received reports from some Omnipod DASH users regarding PDM battery issues, including battery swelling, fluid leaking from the battery, and, in rare cases, extreme overheating which may pose a fire hazard. Our investigation has determined that the Omnipod DASH PDM is at increased risk if charged to full capacity, particularly, if left to charge for extended periods of time (e.g. overnight). Omnipod DASH PDMs in use more than 18 months may have an increased likelihood of this issue occurring.

Solution: We have identified an update to the Omnipod DASH PDM that will address this issue. We expect to begin shipping updated Omnipod DASH PDMs to current customers in the coming months.

You do not need to call to receive an updated Omnipod DASH PDM, one will automatically be shipped to you when available.

Until you receive your updated Omnipod DASH PDM, please follow the actions below:

Actions to Users:

If you experience any of the following issues, **do not** charge your Omnipod DASH PDM, and promptly contact Insulet's dedicated Customer Care team at 0800 011 6132:

- The Omnipod DASH PDM back cover is bulging or cannot close. You may need to remove the PDM gel skin to observe any of these issues. Do not apply pressure to the back cover if it is deformed in any way.
- The Omnipod DASH PDM experiences extreme overheating (uncomfortable to hold) or emits an odour while charging, during use, or in storage.

- The Omnipod DASH PDM does not turn on within 45 minutes of being connected to the charger or turns off immediately after being removed from the charger. If your PDM battery loses its charge very quickly (more than you have previously experienced) or if it takes more than 1.5 hours to reach 80% charge, contact Insulet's Customer Care team.

Continue to use your Omnipod DASH PDM if you do not experience any of the symptoms listed above and follow the actions below to reduce the risk of PDM battery issues:

- Do NOT remove the battery from the Omnipod DASH PDM for any reason, even if the User Guide recommends it for troubleshooting. If you are in a situation where removal of the battery is recommended by the User Guide or PDM screen message, do not remove the battery and contact Insulet's Customer Care team at 0800 011 6132.
- Do NOT continue charging the Omnipod DASH PDM after it reaches 85% of charge. This means you should not charge your device overnight and you should monitor the device while charging.
- Do NOT charge the PDM if the surrounding temperature is 31°C or higher. Do not charge the PDM in direct sunlight.
- If the Omnipod DASH PDM is unusually warm, leave the PDM unplugged and idle at room temperature until it cools down. Do not charge the PDM when it feels unusually warm to the touch.
- Do NOT use your Omnipod DASH PDM while it is charging.
- Always inspect your Omnipod DASH PDM before charging (remove gel skin / cover) for any deformity, back cover bulging, battery leakage, signs of damage at the charging port, or difficulty closing the back cover.

We understand this may impact your experience and are here to support you. We will notify you when we start to ship the updated Omnipod DASH PDMs.

If you have any questions regarding the information provided in this Field Safety Notification, please visit our website at <http://omnipod.com/en-gb/fsn-10-2022> or call 0800 011 6132 to speak to the Insulet Customer Care team.

Please electronically confirm your understanding of this Field Safety Notification by clicking on the link below and follow the instructions on screen - you will continue to receive this e-mail periodically until Insulet receives your acknowledgement.

[Acknowledge Here](#)

Sincerely,

Michael Spears
Insulet Corporation
Snr Vice President,
Regulatory Affairs and Compliance



17th October 2022

URGENT: FIELD SAFETY NOTICE

Please read this notice in its entirety and acknowledge receipt and understanding of this notice.

Dear Valued Healthcare Professional,

We are writing with important safety information regarding the Omnipod DASH® Personal Diabetes Manager (PDM). We have received reports from some Omnipod DASH users regarding PDM battery issues, including battery swelling, fluid leaking from the battery, and in rare cases, extreme overheating which may pose a fire hazard.

The attached notice <http://omnipod.com/en-gb/fsn-10-2022> has been sent as a voluntary Field Safety Notification to all known users of the Omnipod DASH Insulin Management System.

Action needed:

1. Please review the attached Field Safety Notification and share this information with appropriate clinical staff at your site.
2. Please share this Field Safety Notification with your patients who are using the Omnipod DASH Insulin Management System.
3. If you and your clinic have Omnipod DASH demonstration or sample devices, please follow the guidance in the Field Safety Notification to ensure they are working appropriately.
4. Please electronically confirm your understanding of this Field Safety Notification by scanning the QR Code below or navigating to the following URL <http://omnipod.com/en-gb/fsn> and entering your last name and customer code as indicated below.

Last Name:

Customer Code:

QR Code

Thank you for your cooperation with this important matter. If you have questions, please contact Omnipod Customer Care at 0800 011 6132.

Sincerely,

Trang Ly
Insulet Corporation
Snr Vice President,
Clinical & Medical Affairs